Test Type: CHRONIC

Route: DOSED WATER

Species/Strain: MICE/B6C3F1/NCTR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C Number: C20116B

Lock Date: 09/08/2009

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.2.0

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Disposition Summary					
Animals Initially In Study	48	48	48	48	
Early Deaths					
Moribund Sacrifice	16	16	23	15	
Natural Death		2	4	4	
Survivors					
Natural Death	1	1		1	
Terminal Sacrifice	31	28	21	28	
Animals Examined Microscopically	48	47	48	48	
ALIMENTARY SYSTEM					
Esophagus	(48)	(46)	(47)	(47)	
Gallbladder	(46)	(43)	(45)	(43)	
Intestine Large, Ascending Colon	(47)	(44)	(45)	(42)	
Goblet Cell, Hyperplasia	2 [1.0]	16 [1.3]	20 [1.6]	19 [1.6]	
Intestine Large, Cecum	(47)	(44)	(44)	(43)	
Hyperplasia, Lymphoid	2 [2.0]				
Goblet Cell, Hyperplasia				1 [1.0]	
Intestine Large, Descending Colon	(47)	(44)	(45)	(43)	
Goblet Cell, Hyperplasia		7 [1.3]	12 [1.5]	17 [1.4]	
Intestine Large, Transverse Colon	(47)	(44)	(45)	(43)	
Goblet Cell, Hyperplasia	4 [1.0]	14 [1.4]	21 [1.7]	22 [1.6]	
Intestine Small, Duodenum	(47)	(44)	(44)	(44)	
Intestine Small, Ileum	(47)	(44)	(45)	(43)	
Hyperplasia, Lymphoid	1 [2.0]				
Intestine Small, Jejunum	(47)	(44)	(43)	(43)	
Hyperplasia, Lymphoid			1 [3.0]	1 [2.0]	
Liver	(47)	(46)	(47)	(46)	
Angiectasis		•		1 [2.0]	
Basophilic Focus	8	6	5	5	
Basophilic Focus, Multiple				1	
Congestion	1 [1.0]				
Cyst	1 [2.0]			1 [2.0]	
Deformity	1				

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Degeneration, Cystic	1 [2.0]				
Eosinophilic Focus	1 [2.0]				
Fatty Change	•				
Infiltration Cellular, Lymphocyte	1 [3.0]	4 [4 0]	0.[4.0]	4 [4 2]	
	1 [1.0]	1 [1.0]	2 [1.0]	4 [1.3]	
Infiltration Cellular, Polymorphonuclear	4 [0 0]	4 [4 0]	4 [4 0]	1 [2.0]	
Inflammation, Chronic Active	1 [2.0]	1 [1.0]	1 [1.0]	3 [2.3]	
Karyomegaly				1 [4.0]	
Mixed Cell Focus	3				
Necrosis		1 [4.0]	1 [2.0]	1 [3.0]	
Tension Lipidosis		7 [1.4]	4 [1.3]	2 [1.0]	
Thrombus		1 [4.0]			
Vacuolization Cytoplasmic	3 [1.0]	2 [1.0]	2 [2.0]	2 [2.0]	
Mesentery	(0)	(4)	(2)	(4)	
Fat, Necrosis		4 [3.8]	2 [2.5]	3 [3.0]	
Pancreas	(47)	(46)	(47)	(45)	
Infiltration Cellular, Lymphocyte	2 [2.0]	3 [1.0]	1 [1.0]	4 [1.5]	
Vacuolization Cytoplasmic	1 [1.0]	2 [1.0]	3 [1.3]	1 [1.0]	
Acinus, Degeneration	3 [1.3]	2 [2.0]			
Duct, Dilatation			1 [4.0]		
Salivary Glands	(48)	(45)	(46)	(45)	
Infiltration Cellular, Lymphocyte	39 [1.3]	31 [1.4]	23 [1.2]	29 [1.2]	
Stomach, Forestomach	(47)	(45)	(45)	(44)	
Epithelium, Hyperplasia	1 [2.0]	. ,	, ,	• •	
Stomach, Glandular	(47)	(44)	(45)	(45)	
Inflammation, Chronic Active	, ,	, ,	1 [2.0]	1 [2.0]	
Epithelium, Hyperplasia	1 [1.0]	2 [1.5]	3 [1.7]	2 [3.0]	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(48)	(47)	(47)	(47)	
Heart	(48)	(47)	(47)	(47)	
Cardiomyopathy	2 [1.0]	, ,	2 [1.0]	1 [1.0]	
Inflammation, Chronic Active	1 [2.0]		r -1		

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

Species/Strain: MICE/B6C3F1/NCTR

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native) **CAS Number: ALOEVLEAFEXT**

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0

(48) 3	(44)			
	(44)			
	(' ')	(46)	(45)	
ū	•	(10)	1	
			•	
		1 [1.0]	. [=.0]	
	1 [2.0]	. []	1 [2.0]	
1 [2.0]	. [=.4]		. []	
	34 [1.4]	32 [1.5]	35 [1.5]	
` '		· ·		
` '		` '		
	(- /	()	,	
, -,		1 [1.0]		
(48)	(45)		(45)	
(` '		
1 [2.0]				
	(46)	(47)	(45)	
,		,	,	
1				
1 [1.0]	3 [1.0]	1 [2.0]	3 [1.0]	
6 [1.8]	6 [1.3]		4 [1.5]	
	1 [2.0]			
(1)	(1)	(3)	(0)	
(.,	(· /	1 [4.0]	(0)	
	1 [2.0] 43 [1.5] (47) 4 [1.8] (47) 9 [1.9] (44) 1 [2.0] (48) 1 [2.0]	1 [2.0] 1 [2.0] 43 [1.5] (47) (44) 4 [1.8] (47) (46) 9 [1.9] (44) 1 [2.0] (48) (45) 1 [1.0] 1 [2.0] 1 [1.0] 6 [1.8] 6 [1.3] 1 [2.0]	1 [2.0] 1 [2.0] 43 [1.5] (47) (44) 4 [1.8] (2 [2.5] (47) (46) (46) 9 [1.9] (44) (46) (46) 1 [2.0] (48) (48) (45) 1 [1.0] (48) (47) (46) (47) (46) (47) (47) (48) (47) (48) (47) (48) (47) (46) (47) (47) (46) (47) (47) (46) (47) (47) (46) (47) (47) (46) (47) (47) (46) (47) (47) (46) (47) (47) (48) (47) (49) (47) (40) (47) (40) (47) (40) (47) (40) (47) (41) (42) (43) (44) (45) (45) (47) (46) (47) (47) (48) (49) (47) (49) (47) (40) (40) (40) (47) (40) (47) (40) (47) (40) (47) (40) (47) (40) (40) (47) (40) (47) (40) (47) (40) (47) (40) (40) (47) (40)	1 [2.0] 1 [2.0]

GENITAL SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

Route: DOSED WATER
Species/Strain: MICE/B6C3F1/NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Coogulating Cland	(4)	(1)	(0)	(0)	
Coagulating Gland Lumen, Dilatation	(1) 1 [4.0]	(1)	(0)	(0)	
Epididymis	(48)	(44)	(46)	(45)	
	(40)	(44)	1 [2.0]	(45)	
Atrophy Degeneration	1 [2.0]		1 [2.0]		
Fibrosis	1 [2.0]		1 [2.0]		
Hypospermia	1 [4.0]	2 [2.0]	2 [2.5]		
Infiltration Cellular, Lymphocyte	1 [4.0]		2 [2.5]		
Inflammation, Chronic Active		2 [2.0]		1 [2 0]	
Spermatocele		1 [2 0]	1 [1.0]	1 [2.0]	
Serosa, Hyperplasia		1 [2.0]	1 [1.0]	1 [2.0]	
Penis	(0)	(1)	(0)		
Inflammation, Chronic Active	(0)	1 [3.0]	(0)	(0)	
Necrosis		1 [3.0] 1 [3.0]			
Ulcer					
Preputial Gland	(47)	1 [2.0]	(46)	(45)	
·	(47)	(44)	5 [1.8]	(45)	
Cyst	4 [2.5]	6 [2.8]		4 [2.5]	
Degeneration	15 [3.2]	11 [2.6]	10 [3.0]	17 [2.8]	
Infiltration Cellular, Lymphocyte Inflammation, Suppurative	3 [1.7]	4 [1.8]	4 [2.3]	5 [1.8]	
Inflammation, Suppurative Inflammation, Chronic Active	2 [3.0]	6 [2.3]	6 [3.3]	1 [2.0]	
	1 [2.0]	4 [2.3]	4 [2.5]		
Bilateral, Cyst Duct, Ectasia	2 [2 7]	6 [0 0]	1 [3.0]		
Fat, Necrosis	3 [3.7]	6 [2.8]	3 [3.7]	4 [4 0]	
Prostate	1 [4.0]	(44)	1 [3.0]	1 [4.0]	
	(47)	(44)	(46)	(44)	
Infiltration Cellular, Lymphocyte	7 [1.0]	7 [1.0]	6 [1.0]	6 [1.0]	
Inflammation, Suppurative			1 [2.0]	4 [4 0]	
Inflammation, Chronic Active	(40)	(44)	(47)	1 [1.0]	
Seminal Vesicle	(48)	(44)	(47)	(44)	
Atrophy		4 [4 0]	1 [2.0]		
Infiltration Cellular, Lymphocyte		1 [1.0]	4 [4 0]		
Inflammation, Suppurative	4 [0 0]		1 [4.0]		
Inflammation, Chronic Active	1 [2.0]	4 [0 0]	4 [0 0]	E [0 0]	
Lumen, Dilatation	5 [3.2]	4 [2.3]	4 [2.8]	5 [2.2]	
Testes	(47)	(44)	(45)	(44)	
Interstitial Cell, Hyperplasia		1 [2.0]		1 [1.0]	

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Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

HEMATOPOIETIC SYSTEM	C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Bone Marrow	Seminiferous Tubule, Degeneration	4 [1.8]	4 [3.3]	11 [2.0]	3 [2.0]	
Hyperplasia 8 2.8 9 2.7 13 2.3 7 3.3 Lymph Node	HEMATOPOIETIC SYSTEM					
Lymph Node	Bone Marrow	(47)	(45)	(47)	(45)	
Axillary, Hyperplasia, Lymphoid 3 [2.3] 2 [2.5] 1 [3.0] Axillary, Infiltration Cellular, Plasma Cell 1 [2.0] 3 [2.7] 1 [3.0] Inguinal, Hyperplasia, Lymphoid 2 [2.0] 1 [2.0] 2 [2.5] 1 [2.0] Lumbar, Eythrophagocytosis 1 [4.0] Lumbar, Hyperplasia, Lymphoid 2 [2.5] 1 [3.0] Lumbar, Hyperplasia, Lymphoid 2 [2.5] Mediastinal, Hyperplasia, Lymphoid 3 [3.0] Pancreatic, Erythrophagocytosis 1 [3.0] Pancreatic, Infiltration Cellular, Plasma Cell 1 [3.0] Renal, Erythrophagocytosis 1 [4.0] Renal, Erythrophagocytosis 1 [4.0] Renal, Infiltration Cellular, Plasma Cell 1 [3.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (48) (45) (45) (49) Hyperplasia, Lymphoid 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 2 [2.5] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 1 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0]	Hyperplasia	8 [2.8]	9 [2.7]	13 [2.3]	7 [3.3]	
Axillary, Infiltration Cellular, Plasma Cell Inguinal, Hyperplasia, Lymphoid 2 [2.0] 3 [2.7] 1 [3.0] Inguinal, Infiltration Cellular, Plasma Cell Lumbar, Erythrophagocytosis Lumbar, Hyperplasia, Lymphoid 1 [1.0] 1 [3.0] Lumbar, Infiltration Cellular, Plasma Cell Lumbar, Infiltration Cellular, Plasma Cell Mediastinal, Hyperplasia, Lymphoid 2 [2.5] Mediastinal, Infiltration Cellular, Plasma Cell 1 [3.0] Pancreatic, Erythrophagocytosis Pancreatic, Erythrophagocytosis Pancreatic, Erythrophagocytosis Pancreatic, Infiltration Cellular, Plasma Cell Renal, Hyperplasia, Lymphoid 1 [3.0] Renal, Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] Lymph Node, Mandibular Lymph Node, Mandibular Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis 5 [2.4] 1 [2.0] Lymph Node, Mesenteric Alian (48) Angiectasis Alian (48) Alian (45) Alian (45) Alian (46) Alian (47) Alian (48) Alian (48) Alian (48) Alian (49) Ali	Lymph Node	(11)	(5)	(9)	(7)	
Inguinal, Hyperplasia, Lymphoid 2 [2.0] 3 [2.7] 1 [3.0] Inguinal, Infiltration Cellular, Plasma Cell 1 [2.0] 2 [2.5] 1 [2.0] 1 [4.0] 1 [4.0] 1 [3.0] 1 [4.0] 1 [3.0] 1 [Axillary, Hyperplasia, Lymphoid	3 [2.3]		2 [2.5]	1 [3.0]	
Inguinal, Infiltration Cellular, Plasma Cell 1 2.0 2 2.5 1 2.0 1 4.0 4.0 1 4.0 1 4.0 1 4.0 1 4.0 1 4.0 1 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4	Axillary, Infiltration Cellular, Plasma Cell			1 [2.0]		
Lumbar, Erythrophagocytosis Lumbar, Hyperplasia, Lymphoid 2 [2.5] Mediastinal, Hyperplasia, Lymphoid Pancreatic, Erythrophagocytosis Pancreatic, Infiltration Cellular, Plasma Cell Renal, Erythrophagocytosis Renal, Erythrophagocytosis Renal, Hyperplasia, Lymphoid 1 [3.0] Renal, Infiltration Cellular, Plasma Cell Lymph Node, Mandibular Lymphoid 9 [1.4] 1 [2.0]	Inguinal, Hyperplasia, Lymphoid	2 [2.0]		3 [2.7]	1 [3.0]	
Lumbar, Hyperplasia, Lymphoid 1 [1.0] 1 [3.0] Lumbar, Infiltration Cellular, Plasma Cell 1 [3.0] Mediastinal, Hyperplasia, Lymphoid 2 [2.5] Mediastinal, Infiltration Cellular, Plasma Cell 1 [3.0] Pancreatic, Erythrophagocytosis 1 [3.0] Pancreatic, Infiltration Cellular, Plasma Cell 1 [3.0] Renal, Erythrophagocytosis 1 [2.0] Renal, Hyperplasia, Lymphoid 1 [3.0] 1 [2.0] Renal, Hyperplasia, Lymphoid 1 [3.0] 1 [2.0] Renal, Infiltration Cellular, Plasma Cell (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 1 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (45) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 2 [2.5] 4 [2.8] Infiltration Cellular, Histiocyte 1 [3.0] 2 [2.0] 1 [3.0] Infiltration Cellular, Plasma Cell 1 [3.0] 1 [3.0] Thombus 1 [3.0]	Inguinal, Infiltration Cellular, Plasma Cell		1 [2.0]	2 [2.5]	1 [2.0]	
Lumbar, Infiltration Cellular, Plasma Cell 1 [3.0] Mediastinal, Hyperplasia, Lymphoid 2 [2.5] Mediastinal, Infiltration Cellular, Plasma Cell 1 [3.0] Pancreatic, Erythrophagocytosis 1 [3.0] Pancreatic, Infiltration Cellular, Plasma Cell 1 [3.0] Renal, Erythrophagocytosis 1 [4.0] Renal, Hyperplasia, Lymphoid 1 [3.0] Renal, Infiltration Cellular, Plasma Cell 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Ce	Lumbar, Erythrophagocytosis				1 [4.0]	
Mediastinal, Hyperplasia, Lymphoid 2 [2.5] Mediastinal, Infiltration Cellular, Plasma Cell 1 [3.0] Pancreatic, Erythrophagocytosis 1 [3.0] Pancreatic, Infiltration Cellular, Plasma Cell 1 [3.0] Renal, Erythrophagocytosis 1 [4.0] Renal, Hyperplasia, Lymphoid 1 [3.0] 1 [2.0] Renal, Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiccyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [2.0]	Lumbar, Hyperplasia, Lymphoid		1 [1.0]		1 [3.0]	
Mediastinal, Infiltration Cellular, Plasma Cell 1 [3.0] Pancreatic, Erythrophagocytosis 1 [3.0] Pancreatic, Infiltration Cellular, Plasma Cell 1 [3.0] Renal, Erythrophagocytosis 1 [2.0] Renal, Hyperplasia, Lymphoid 1 [3.0] 1 [2.0] Renal, Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell	Lumbar, Infiltration Cellular, Plasma Cell				1 [3.0]	
Pancreatic, Erythrophagocytosis Pancreatic, Infiltration Cellular, Plasma Cell Renal, Erythrophagocytosis Renal, Hyperplasia, Lymphoid 1 [3.0] Renal, Hyperplasia, Lymphoid 1 [3.0] Renal, Infiltration Cellular, Plasma Cell Lymph Node, Mandibular Hyperplasia, Lymphoid 9 [1.4] 1 [2.0] 1 [2.0] 1 [2.0] 1 [2.0] 1 [2.0] 1 [2.0] 1 [2.0] 1 [2.0] 1 [3.0] 1 [2.0] 1 [2.0] 1 [2.0] 1 [3.0] 1 [2.0] 1 [3.0]	Mediastinal, Hyperplasia, Lymphoid	2 [2.5]				
Pancreatic, Infiltration Cellular, Plasma Cell Renal, Erythrophagocytosis Renal, Hyperplasia, Lymphoid 1 [3.0] Renal, Infiltration Cellular, Plasma Cell Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell Lymph Node, Mesenteric Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Plasma Cell Infiltration Cellular, Ploymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus	Mediastinal, Infiltration Cellular, Plasma Cell	1 [3.0]				
Renal, Erythrophagocytosis 1 [4.0] Renal, Hyperplasia, Lymphoid 1 [3.0] 1 [2.0] Renal, Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [2.0] 1 [4.0] 1 [4.0]	Pancreatic, Erythrophagocytosis				1 [3.0]	
Renal, Hyperplasia, Lymphoid 1 [3.0] 1 [2.0] Renal, Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] 1 [2.0] (43) Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 27 [2.5] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [2.5] 1 [3.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [2.0] 1 [4.0]	Pancreatic, Infiltration Cellular, Plasma Cell				1 [3.0]	
Renal, Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] 2 [2.5] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 27 [2.5] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Renal, Erythrophagocytosis				1 [4.0]	
Lymph Node, Mandibular (47) (44) (45) (44) Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] (45) (43) Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Renal, Hyperplasia, Lymphoid	1 [3.0]		1 [2.0]		
Hyperplasia, Lymphoid 9 [1.4] 5 [2.0] 4 [1.0] 2 [2.0] Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [2.0] 1 [3.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Renal, Infiltration Cellular, Plasma Cell			1 [2.0]	1 [2.0]	
Infiltration Cellular, Plasma Cell 1 [2.0] 1 [2.0] 1 [2.0] Pigmentation 1 [2.0] 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [2.0] 1 [3.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Lymph Node, Mandibular	(47)	(44)	(45)	(44)	
Pigmentation 1 [2.0] Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Hyperplasia, Lymphoid	9 [1.4]	5 [2.0]	4 [1.0]	2 [2.0]	
Lymph Node, Mesenteric (48) (45) (45) (43) Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Infiltration Cellular, Plasma Cell		1 [2.0]	1 [2.0]	1 [2.0]	
Angiectasis 5 [2.4] 1 [2.0] 2 [2.5] 1 [2.0] Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [4.0]	Pigmentation		1 [2.0]			
Hematopoietic Cell Proliferation 1 [2.0] 1 [2.0] Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Lymph Node, Mesenteric	(48)	(45)	(45)	(43)	
Hemorrhage 10 [2.2] 13 [2.2] 10 [2.4] 11 [2.2] Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Angiectasis	5 [2.4]	1 [2.0]	2 [2.5]	1 [2.0]	
Hyperplasia, Lymphoid 28 [2.1] 17 [2.0] 17 [2.2] 23 [2.3] Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Hematopoietic Cell Proliferation	1 [2.0]			1 [2.0]	
Infiltration Cellular, Histiocyte 2 [2.5] 4 [2.8] Infiltration Cellular, Plasma Cell 2 [4.0] Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0]	Hemorrhage	10 [2.2]	13 [2.2]	10 [2.4]	11 [2.2]	
Infiltration Cellular, Plasma Cell2 [4.0]Infiltration Cellular, Polymorphonuclear1 [3.0]2 [2.0]1 [3.0]Thrombus1 [2.0]1 [4.0]		28 [2.1]	17 [2.0]	17 [2.2]	23 [2.3]	
Infiltration Cellular, Polymorphonuclear 1 [3.0] 2 [2.0] 1 [3.0] Thrombus 1 [2.0] 1 [4.0]	Infiltration Cellular, Histiocyte			2 [2.5]	4 [2.8]	
Thrombus 1 [2.0] 1 [4.0]	Infiltration Cellular, Plasma Cell				2 [4.0]	
· ·	Infiltration Cellular, Polymorphonuclear		1 [3.0]	2 [2.0]	1 [3.0]	
Sinus, Dilatation 6 [2.7] 2 [3.0] 4 [2.8] 2 [2.0]	Thrombus		1 [2.0]		1 [4.0]	
	Sinus, Dilatation	6 [2.7]	2 [3.0]	4 [2.8]	2 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Spleen	(48)	(45)	(46)	(44)	
Angiectasis	1 [2.0]	(10)	1 [2.0]	()	
Depletion Lymphoid	. [=.0]		1 [4.0]		
Hematopoietic Cell Proliferation	20 [3.6]	15 [3.7]	18 [3.5]	14 [3.4]	
Hyperplasia, Lymphoid	24 [2.2]	21 [2.1]	20 [2.3]	22 [2.5]	
Pigmentation			1 [2.0]	,	
Thymus	(41)	(39)	(37)	(40)	
Atrophy	22 [3.2]	19 [2.9]	17 [3.1]	23 [2.7]	
Hyperplasia, Lymphoid	2 [2.0]	1 [1.0]	[0]	1 [1.0]	
Mineralization	- []	. []	1 [1.0]	1,111	
INTEGUMENTARY SYSTEM					
Skin	(48)	(47)	(46)	(48)	
Fibrosis	(10)	1 [3.0]	4 [4.0]	(10)	
Hemorrhage		1 [0.0]	1 [1.0]	1 [4.0]	
Hyperplasia, Basal Cell			1 [4.0]	. [0]	
Inflammation, Suppurative	1 [3.0]	2 [1.0]	3 [2.0]	1 [2.0]	
Inflammation, Chronic	. [0.0]	2[0]	1 [2.0]	. [2.0]	
Inflammation, Chronic Active	1 [1.0]	3 [1.0]	4 [2.0]	2 [3.0]	
Metaplasia, Osseous	. [0]	0[1.0]	1 [2.0]	_ [0.0]	
Mineralization	1 [4.0]	1 [2.0]	1 [3.0]		
Necrosis	. [•]	. [2.0]	. [0.0]	1 [2.0]	
Ulcer	1 [4.0]		4 [3.0]	3 [2.3]	
Epithelium, Hyperplasia	1 [2.0]	6 [1.8]	4 [2.0]	4 [2.0]	
MUSCULOSKELETAL SYSTEM					
Skeletal Muscle	(1)	(1)	(3)	(0)	
NERVOUS SYSTEM					
Brain, Cerebrum Mineralization	(47) 29 [1.3]	(46) 24 [1.1]	(46) 24 [1.1]	(43) 24 [1.2]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Fibrosis

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

Species/Strain: MICE/B6C3F1/NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0 RESPIRATORY SYSTEM (47)(47)(48)(46)Lung Congestion 1 [4.0] Infiltration Cellular, Histiocyte 5 [2.6] 2 [2.5] Infiltration Cellular, Lymphocyte 1 [2.0] Inflammation, Chronic Active 1 [1.0] **Thrombus** 1 [1.0] Alveolar Epithelium, Hyperplasia 5 [2.6] 4 [1.8] 2 [2.0] (47)(47)(48)(47)Nose Hyaline Droplet 6 [1.2] 31 [1.8] 39 [2.0] 13 [1.8] Posterior To Upper Incisor, Dysplasia 1 [4.0] 1 [4.0] Trachea (48)(47)(46)(45)SPECIAL SENSES SYSTEM (47)Eye (43)(44)(43)Cataract 1 [1.0] 1 [1.0] Cornea, Hyperplasia 1 [2.0] Cornea, Inflammation, Chronic Active 1 [1.0] Harderian Gland (48)(44)(46)(44)Infiltration Cellular, Lymphocyte 1 [1.0] 2 [2.0] 3 [1.7] 2 [1.5] Inflammation, Chronic Active 1 [1.0] Acinus, Degeneration 1 [3.0] 1 [2.0] Acinus, Dilatation 1 [2.0] Epithelium, Hyperplasia 1 [2.0] **URINARY SYSTEM** (45)Kidney (48)(46)(45)Cyst 3 [2.7] 2 [1.5] Cyst Multilocular 1 [4.0]

1 [3.0]

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Liveline Proplet			2 [2 2]		
Hyaline Droplet	40.54.41	0.14.41	3 [3.3]	40.14.03	
Infiltration Cellular, Lymphocyte	10 [1.4]	8 [1.4]	10 [1.3]	12 [1.3]	
Inflammation, Chronic Active				1 [2.0]	
Metaplasia, Osseous	2 [1.5]		2 [1.0]		
Nephropathy	26 [1.3]	18 [1.2]	17 [1.2]	20 [1.3]	
Pigmentation			1 [2.0]		
Pelvis, Dilatation		1 [2.0]	1 [2.0]		
Urethra	(1)	(0)	(0)	(1)	
Bulbourethral Gland, Dilatation	1 [4.0]				
Bulbourethral Gland, Infiltration Cellular, Lymphocyte	1 [2.0]				
Urinary Bladder	(48)	(45)	(45)	(44)	
Infiltration Cellular, Lymphocyte	3 [1.0]	2 [1.0]	2 [1.0]	2 [1.0]	
Inflammation, Chronic Active				1 [4.0]	
Lumen, Dilatation	3 [3.3]	1 [4.0]	1 [3.0]	1 [2.0]	

^{***} END OF MALE ***

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Disposition Summary					
Disposition Summary					
Animals Initially In Study	48	48	48	48	
Early Deaths					
Moribund Sacrifice	6	12	8	6	
Natural Death	5	4	3	5	
Survivors					
Moribund Sacrifice	1	1		1	
Natural Death		1	1	2	
Terminal Sacrifice	35	30	36	34	
Animals Examined Microscopically	47	48	48	48	
ALIMENTARY SYSTEM					
Gallbladder	(42)	(43)	(44)	(41)	
Intestine Large, Ascending Colon	(43)	(43)	(44)	(43)	
Goblet Cell, Hyperplasia	1 [1.0]	15 [1.2]	20 [1.3]	25 [1.7]	
Intestine Large, Cecum	(42)	(43)	(44)	(42)	
Hyperplasia, Lymphoid	1 [1.0]		, ,	, ,	
Goblet Cell, Hyperplasia	1 [1.0]		2 [1.5]	2 [1.5]	
Intestine Large, Descending Colon	(43)	(43)	(44)	(43)	
Goblet Cell, Hyperplasia	, ,	4 [1.3]	7 [1.4]	17 [1.6]	
Intestine Large, Rectum	(43)	(43)	(44)	(42)	
Intestine Large, Transverse Colon	(42)	(42)	(44)	(43)	
Goblet Cell, Hyperplasia	2 [1.0]	18 [1.2]	23 [1.3]	26 [1.7]	
Intestine Small, Duodenum	(43)	(43)	(44)	(42)	
Intestine Small, Ileum	(42)	(43)	(44)	(42)	
Hyperplasia, Lymphoid			1 [3.0]	1 [3.0]	
Intestine Small, Jejunum	(42)	(43)	(44)	(42)	
Liver	(45)	(44)	(46)	(46)	
Autolysis				1 [4.0]	
Basophilic Focus	1		1	4	
Clear Cell Focus		1			
Cyst, Multiple				1 [4.0]	
Cytomegaly		1 [2.0]			
Eosinophilic Focus	1			1	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

Route: DOSED WATER
Species/Strain: MICE/B6C3F1/NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Hematopoietic Cell Proliferation	1 [3.0]	1 [1.0]		2 [1.0]	
Infiltration Cellular, Lymphocyte	10 [1.8]	6 [1.2]	6 [1.7]	9 [1.4]	
Inflammation, Chronic Active	6 [1.7]	5 [2.2]	4 [1.3]	5 [1.2]	
Mixed Cell Focus	1		1	1	
Necrosis	3 [2.3]	2 [3.5]	2 [3.0]	3 [3.3]	
Pigmentation	1 [2.0]		1 [2.0]		
Tension Lipidosis	7 [1.6]	5 [1.4]	2 [1.0]	5 [1.2]	
Vacuolization Cytoplasmic	12 [1.5]	14 [1.8]	12 [1.4]	16 [1.7]	
Bile Duct, Hyperplasia		1 [2.0]			
Oval Cell, Hyperplasia	1 [3.0]				
Parenchyma, Degeneration	11		1 [4.0]		
Mesentery	(6)	(8)	(9)	(3)	
Angiectasis	(-)	(-)	1 [3.0]	(-)	
Infiltration Cellular, Lymphocyte			1 [3.0]		
Inflammation, Chronic Active			1 [4.0]		
Fat, Hemorrhage	1 [4.0]		. []	1 [4.0]	
Fat, Infiltration Cellular, Histiocyte	. [•]			1 [4.0]	
Fat, Necrosis	6 [2.8]	8 [3.1]	8 [3.1]	2 [3.5]	
Oral Mucosa	(1)	(0)	(0)	(0)	
Pancreas	(42)	(43)	(44)	(43)	
Cyst	(/	(10)	(· · /	1 [2.0]	
Hemorrhage				1 [4.0]	
Infiltration Cellular, Lymphocyte	11 [1.5]	4 [1.3]	13 [1.2]	15 [1.5]	
Vacuolization Cytoplasmic	1 [1.0]	2 [2.0]	. • [=]		
Acinus, Degeneration	1 [4.0]	1 [2.0]	1 [2.0]		
Duct, Dilatation	. [•]	. [=.0]	1 [4.0]	1 [4.0]	
Salivary Glands	(43)	(43)	(44)	(43)	
Infiltration Cellular, Lymphocyte	29 [1.6]	31 [1.3]	31 [1.4]	26 [1.5]	
Stomach, Forestomach	(43)	(44)	(45)	(42)	
Keratin Cyst	1	1	(10)	·/	
Epithelium, Hyperplasia	•	2 [2.0]	1 [2.0]	1 [2.0]	
Stomach, Glandular	(43)	(44)	(45)	(42)	
Cyst	1 [2.0]	(' ')	(10)	(/	
Erosion	, [=,v]			1 [2.0]	
Inflammation, Chronic Active		1 [1.0]		. [=.0]	
Epithelium, Hyperplasia		1 [3.0]	3 [2.3]	4 [1.8]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08
First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

Route: DOSED WATER
Species/Strain: MICE/B6C3F1/NCTR

Follicular Cell, Hyperplasia

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0 CARDIOVASCULAR SYSTEM Heart (45)(46)(46)(44)Cardiomyopathy 4 [1.3] 2 [1.0] 3 [1.0] Inflammation, Chronic Active 1 [1.0] Mineralization 1 [1.0] **ENDOCRINE SYSTEM** Adrenal Cortex (44)(43)(44)(44)Vacuolization Cytoplasmic 4 [2.5] 4 [2.3] 1 [4.0] 1 [2.0] Subcapsular, Hyperplasia 43 [2.0] 43 [1.9] 43 [2.0] 44 [2.0] Adrenal Medulla (44)(42)(44)(44)Hyperplasia 1 [3.0] 1 [1.0] Pigmentation 1 [2.0] Islets, Pancreatic (42)(43)(44)(43)Hyperplasia 1 [1.0] 5 [1.8] 1 [2.0] 2 [2.0] Parathyroid Gland (42)(37)(42)(40)Cyst 1 [1.0] 1 [1.0] Infiltration Cellular, Lymphocyte 1 [2.0] Pituitary Gland (43)(38)(41)(44)**Thrombus** 1 [3.0] Pars Distalis, Angiectasis 1 [2.0] 1 [2.0] Pars Distalis, Cyst 1 [2.0] 2 [2.0] Pars Distalis, Hyperplasia 7 [1.6] 8 [1.4] 10 [2.2] 11 [1.8] Pars Intermedia, Angiectasis 1 [3.0] Thyroid Gland (43)(43)(44)(43)Cyst 1 [2.0] 1 [2.0] **Ectopic Thymus** 1 3 [1.3] Infiltration Cellular, Lymphocyte 1 [1.0] 2 [1.0] 6 [1.2] Inflammation, Suppurative 1 [1.0] Inflammation, Chronic Active 1 [1.0] Follicle, Degeneration 6 [1.5] 10 [1.3] 9 [1.3] 6 [1.3]

3 [3.0]

1 [2.0]

1 [2.0]

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 **First Dose M/F:** 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Follicular Cell, Hypertrophy	1 [3.0]				
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland	(44)	(44)	(44)	(42)	
Degeneration	43 [3.9]	44 [3.8]	43 [3.9]	40 [3.8]	
Ovary	(44)	(46)	(45)	(44)	
Atrophy	40 [3.9]	39 [3.9]	40 [3.9]	39 [3.8]	
Autolysis		1 [4.0]			
Cyst	14 [3.1]	18 [3.1]	12 [3.0]	9 [2.7]	
Cyst, Multiple	1 [4.0]		2 [2.0]	2 [4.0]	
Hemorrhage			1 [2.0]		
Uterus	(46)	(45)	(44)	(45)	
Angiectasis			1 [3.0]		
Autolysis	1 [4.0]			1 [4.0]	
Edema	1 [4.0]				
Hydrometra		1 [4.0]		1 [4.0]	
Thrombus		1 [2.0]	1 [2.0]	1 [4.0]	
Endometrium, Hyperplasia, Cystic	43 [3.0]	44 [2.8]	43 [3.1]	43 [2.9]	
Lumen, Dilatation	1 [4.0]				
HEMATOPOIETIC SYSTEM					
Bone Marrow	(43)	(43)	(44)	(43)	
Fibrosis	1 [2.0]	,	` '	` '	
Hyperplasia	7 [2.6]	5 [2.8]	5 [2.4]	3 [2.0]	
Lymph Node	(14)	(15)	(12)	(13)	
Axillary, Infiltration Cellular, Polymorphonuclear		1 [3.0]	·		
Iliac, Hyperplasia, Lymphoid				1 [2.0]	
Iliac, Infiltration Cellular, Plasma Cell				1 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 **First Dose M/F:** 04/19/05 / 04/19/05

Lab: NCTR

Route: DOSED WATER
Species/Strain: MICE/B6C3F1/NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Iliac, Infiltration Cellular, Polymorphonuclear				1 [2.0]	
Lumbar, Hemorrhage				2 [2.0]	
Lumbar, Hyperplasia, Lymphoid	3 [2.3]		1 [2.0]	5 [1.8]	
Lumbar, Infiltration Cellular, Plasma Cell	1 [3.0]		1 [3.0]	3 [1.0]	
Lumbar, Infiltration Cellular, Polymorphonuclear	2 [2.5]	1 [3.0]	1 [0.0]		
Lumbar, Sinus, Dilatation				1 [2.0]	
Renal, Hemorrhage				1 [4.0]	
Renal, Hyperplasia, Lymphoid	2 [2.5]			1 [3.0]	
Renal, Infiltration Cellular, Polymorphonuclear	2 [2.0]				
Lymph Node, Mandibular	(43)	(44)	(45)	(43)	
Amyloid Deposition	, ,	1 [2.0]	, ,	, ,	
Hyperplasia, Lymphoid	11 [1.8]	13 [1.5]	12 [1.9]	14 [2.1]	
Infiltration Cellular, Lymphocyte		1 [1.0]			
Infiltration Cellular, Plasma Cell	1 [2.0]	2 [2.5]			
Infiltration Cellular, Polymorphonuclear	1 [2.0]		1 [2.0]		
Lymph Node, Mesenteric	(43)	(45)	(43)	(42)	
Amyloid Deposition		1 [2.0]			
Angiectasis	1 [4.0]		1 [2.0]		
Hemorrhage		1 [2.0]		2 [3.0]	
Hyperplasia, Lymphoid	10 [2.0]	12 [1.8]	14 [1.8]	16 [1.5]	
Infiltration Cellular, Plasma Cell	1 [2.0]	2 [2.5]			
Sinus, Dilatation				1 [2.0]	
Spleen	(44)	(46)	(45)	(44)	
Amyloid Deposition		1 [3.0]			
Depletion Lymphoid				1 [3.0]	
Fibrosis, Stromal	1 [4.0]				
Hematopoietic Cell Proliferation	16 [3.1]	13 [2.8]	9 [3.3]	12 [2.7]	
Hyperplasia, Lymphoid	20 [2.7]	23 [2.5]	21 [2.9]	24 [3.1]	
Necrosis			1 [4.0]		
Pigmentation	3 [2.0]	4 [2.0]	4 [2.3]	5 [2.2]	
Thrombus	1 [4.0]				
Thymus	(41)	(44)	(43)	(41)	
Amyloid Deposition		1 [2.0]			
Atrophy	10 [3.1]	14 [2.4]	17 [2.4]	10 [2.5]	
Cyst				1 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

Species/Strain: MICE/B6C3F1/NCTR

CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
8 [2.3] 1 [2.0]	7 [1.9]	8 [1.9]	12 [1.8]	
. [=.0]			1 [3.0]	
(44)	(43)	(44)	(44)	
1 [2.0]				
		1 [2.0]	1 [2.0]	
2 [2.0]		2 [2.0]		
4 [2.3]	3 [1.7]		3 [2.3]	
(44)	(46)	(45)	(44)	
		1 [3.0]		
(47)	(46)	(48)	(46)	
1 [2.0]	· ·			
		1 [4.0]		
(43)	(44)	(44)	(43)	
	· ·			
` '	,	,		
(43)	(44)	(44)		
` '	, ,	, ,		
24 [1.2]	30 [1.1]	24 [1.2]		
	8 [2.3] 1 [2.0] (44) 1 [2.0] 2 [2.0] 4 [2.3] (44)	8 [2.3] 7 [1.9] 1 [2.0] (43) 2 [2.0] 3 [1.7] 4 [2.3] 3 [1.7] (44) (46) (47) (46) 1 [2.0] 1 [3.0] (0) (2) (43) (44) 2 [2.0] 1 [1.0] (43) (44) (43) (44) (43) (44) (43) (44) (43) (44) (43) (44) (43) (44) (43) (44) (43) (44) (43) (44)	8 [2.3] 7 [1.9] 8 [1.9] (44) (43) (44) 1 [2.0] 1 [2.0] 2 [2.0] 2 [2.0] 4 [2.3] 3 [1.7] 3 [1.7] (44) (46) (45) 1 [3.0] 2 [1.5] (0) (2) (2) 1 [4.0] (43) (44) (44) 2 [2.0] 1 [1.0] 2 [2.5] (43) (44) (44) (43) (44) (44) (43) (44) (44) (43) (44) (44) (43) (44) (44) (43) (44) (44)	8 [2.3] 7 [1.9] 8 [1.9] 12 [1.8] 1 [2.0] 1 [3.0] (44) (43) (44) (44) 1 [2.0] 1 [2.0] 1 [2.0] 2 [2.0] 2 [2.0] 4 [2.3] 3 [1.7] 3 [1.7] 3 [2.3] (44) (46) (45) (44) 1 [3.0] (47) (46) (48) (45) (44) 1 [3.0] (47) (2) (2) (0) (48) (49) (49) (49) (49) (49) (49) (40) (40) (40) (41) (41) (43) (44) (44) (43) 2 [2.0] 1 [1.0] 2 [2.5] 1 [2.0] (43) (44) (44) (43) (43) (44) (44) (43) (43) (44) (44) (43) (43) (44) (44) (43) (43) (44) (44) (43)

RESPIRATORY SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 **First Dose M/F:** 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0	
Lung	(45)	(45)	(46)	(44)	
Lung	(45)	(45)	(46)	(44)	
Autolysis Congestion	1 [4.0]		1 [4.0]	1 [4.0]	
Hemorrhage	2 [3.0]	1 [4.0]		1 [4.0]	
Infiltration Cellular, Histiocyte	2 [3.0] 5 [2.4]	4 [2.0]	3 [1.7]	1 [1.0]	
Infiltration Cellular, Lymphocyte	3 [2.4] 4 [1.8]	4 [2.0] 2 [1.5]	2 [2.0]	3 [1.7]	
Inflammation, Chronic	4 [1.0]	2 [1.5] 1 [1.0]	2 [2.0]	3[1.7]	
Inflammation, Chronic Active	2 [2.5]	1 [2.0]		1 [2.0]	
Metaplasia, Osseous	2 [2.0]	1 [2.0] 1 [1.0]		1 [2.0]	
Mineralization		1 [1.0]	1 [1.0]		
Alveolar Epithelium, Hyperplasia			2 [3.0]	1 [1.0]	
Nose	(45)	(44)	2 [3.0] (45)	(45)	
Hyaline Droplet	12 [1.3]	12 [1.2]	(43) 17 [1.1]	9 [1.6]	
Inflammation, Chronic Active	1 [2.0]	12 [1.2]	17 [1.1]	9 [1.0]	
illianimation, Chronic Active	1 [2.0]				
SPECIAL SENSES SYSTEM					
Eye	(42)	(43)	(44)	(42)	
Cataract	2 [1.0]		2 [1.0]	, ,	
Phthisis Bulbi		1 [4.0]			
Cornea, Inflammation, Chronic Active	1 [2.0]				
Cornea, Ulcer	1 [4.0]				
Harderian Gland	(43)	(43)	(44)	(43)	
Hyperplasia			, ,	1 [2.0]	
Infiltration Cellular, Lymphocyte	6 [1.2]	5 [1.0]	5 [1.0]	5 [1.2]	
Epithelium, Hyperplasia		2 [1.5]			
Lacrimal Gland	(1)	(0)	(0)	(0)	
Infiltration Cellular, Lymphocyte	1 [2.0]				
URINARY SYSTEM					
Kidney	(44)	(43)	(46)	(44)	
Amyloid Deposition	1 [4.0]	1 [4.0]	()	2 [3.5]	
Autolysis	1 [4.0]	. [•]		1 [4.0]	
Cyst, Multiple	. [•]	1 [4.0]		. [0]	
- ,,		. []			

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: CHRONIC

Route: DOSED WATER

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 01/15/2010 AVERAGE SEVERITY GRADES[b]

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Time Report Requested: 14:39:08 First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0		
					·	
Hyaline Droplet	3 [3.0]	1 [3.0]	1 [3.0]	1 [3.0]		
Infiltration Cellular, Histiocyte	1 [1.0]					
Infiltration Cellular, Lymphocyte	22 [1.5]	23 [1.1]	22 [1.2]	27 [1.5]		
Metaplasia, Osseous			3 [1.7]	2 [1.5]		
Nephropathy	5 [1.6]	6 [1.7]	7 [1.1]	6 [1.7]		
Polyarteritis				1 [2.0]		
Pelvis, Dilatation		1 [3.0]	2 [3.5]			
Pelvis, Mineralization		1 [2.0]				
Transitional Epithelium, Hyperplasia		1 [2.0]				
Urinary Bladder	(43)	(43)	(44)	(42)		
Infiltration Cellular, Lymphocyte	22 [1.2]	22 [1.0]	22 [1.3]	25 [1.3]		
Lumen, Dilatation			1 [3.0]			

^{***} END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)